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|--|--|---|--|---|--|
| FORM PTO 1390<br>(REV. 10-2003)  |  | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE |  | ATTORNEY'S DOCKET NUMBER<br>ASZD-P01-724                            |  |
| TRANSMITTAL LETTER TO THE UNITED STATES<br>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br>CONCERNING A FILING UNDER 35 U.S.C. 371 |  |   |  | 10/505231<br>U.S. PATENT APPLICATION NO. (If known, see 37 CFR 1.5) |  |
| INTERNATIONAL APPLICATION NO.<br>PCT/GB03/00803  |  | INTERNATIONAL FILING DATE<br>24 February 2003           |  | PRIORITY DATE CLAIMED<br>26 February 2002                           |  |
| TITLE OF INVENTION PHARMACEUTICAL FORMULATION OF IRESSA COMPRISING A WATER-SOLUBLE CELLULOSE DERIVATIVE                    |  |   |  |   |  |
| APPLICANT(S) FOR DO/EO/US Gellert et al.   |  |   |  |   |  |

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
- ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing 35 U.S.C. 371.
- ☒ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☒ The US has been elected (Article 31).
- ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - ☐ is attached hereto (required only if not communicated by the International Bureau).
  - ☒ has been communicated by the International Bureau.
  - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
- ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
  - ☐ is attached hereto.
  - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - ☐ are attached hereto (required only if not communicated by the International Bureau).
  - ☐ have been communicated by the International Bureau.
  - ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - ☒ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
- ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
- ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

- ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☐ A preliminary amendment.
- ☒ An Application Data Sheet under 37 CFR 1.76.
- ☒ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
- ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
- ☒ Other items or information: Return Receipt Postcard  
Marked-Up Specification  
Copy of PCT/GB03/00803

DTOS Rec'd PCT/PTO 19 AUG 2004

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|--|--|---|--------------|--|----------|
| U.S. APPLICATION NO. <b>10/505231</b>  |  | INTERNATIONAL APPLICATION NO.<br>PCT/GB03/00803 |              | ATTORNEY'S DOCKET NUMBER<br>ASZD-P01-724                                     |          |
| 21. <input checked="" type="checkbox"/> The following fees are submitted:  |  |   |              | CALCULATIONS PTO USE ONLY  |          |
| <b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) – (5)):</b><br><input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO .....\$1080.00<br><input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO .....\$920.00<br><input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO .....\$770.00<br><input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) .....\$730.00<br><input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) .....\$100.00 |  |   |              |  |          |
| ENTER APPROPRIATE BASIC FEE AMOUNT =   |  |   |              | \$   | 920.00   |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).  |  |   |              | \$   |          |
| CLAIMS   |  | NUMBER FILED                                    | NUMBER EXTRA | RATE   |          |
| Total claims   |  | -20 =   |              | x  | \$       |
| Independent claims   |  | -3 =  |              | x  | \$       |
| MULTIPLE DEPENDENT CLAIM(s) (if applicable)  |  |   |              | +  | \$       |
| TOTAL OF ABOVE CALCULATIONS =  |  |   |              | \$   | 920.00   |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.   |  |   |              | \$   |          |
| SUBTOTAL =   |  |   |              | \$   | 920.00   |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).   |  |   |              | \$   |          |
| TOTAL NATIONAL FEE =   |  |   |              | \$   | 920.00   |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  |  |   |              | +  | \$ 40.00 |
| TOTAL FEES ENCLOSED =  |  |   |              | \$   | 960.00   |
|  |  |   |              | Amount to be refunded:   | \$       |
|  |  |   |              | charged:   | \$       |
| a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.   |  |   |              |  |          |
| b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>18-1945</u> in the amount of \$ <u>960.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.  |  |   |              |  |          |
| c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>18-1945</u> . A duplicate copy of this sheet is enclosed.  |  |   |              |  |          |
| d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.  |  |   |              |  |          |
| <b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.   |  |   |              |  |          |
| SEND ALL CORRESPONDENCE TO:<br>Patricia Granahan, Sc.D.<br>ROPES & GRAY LLP<br>One International Place<br>Boston, Massachusetts 02110-2624<br>(617) 951-7449<br>CUSTOMER NUMBER: 28120   |  |   |              | SIGNATURE: <u>David P. Halstead</u><br>NAME<br>44,735<br>REGISTRATION NUMBER |          |

Application No. (if known): Not Yet Assigned

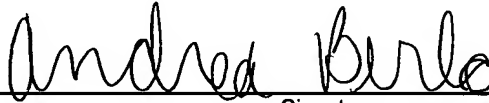
Attorney Docket No.: ASZD-P01-724

**Certificate of Express Mailing Under 37 CFR 1.10**

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV543599418US in an envelope addressed to:

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on August 19, 2004  
Date



Signature

Andrea Berlo

Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Transmittal Letter to the United States Designated-Elected Office (2 pages)

Application Data Sheet ( 3 pages)

Substitute Specification (54 pages)

Marked-Up Specification (55 pages)

Preliminary Amendment (4 pages)

Executed Declaration (4 pages)

Recordation Form Cover Sheet (1 page)

Assignment (2 pages)

IDS (2 pages)

Form SB/08 (1 page)

Copies of Reference s AA-AB, BA-BB

Copy of PCT/GB03/00803

Charge \$960.00 to deposit account 18-1945

Return receipt postcard